DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 27, 2014

FloSpine, LLC
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K141850
Trade/Device Name: Canaveral Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP
Dated: September 26, 2014
Received: September 29, 2014

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141850

Device Name
Canaveral Pedicle Screw System

Indications for Use *(Describe)*
The FloSpine Canaveral Pedicle System is intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.
When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Canaveral Pedicle Screw System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Canaveral Pedicle Screw System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to the posterior approach.
The Canaveral Pedicle Screw System is indicated to provide the surgeon with a minimally invasive approach for posterior spine surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K141850

Date Prepared:	October 21, 2014
Contact:	James Spitler FloSpine, LLC 9288 Lake Serena Dr. Boca Raton, FL 33496 561-705-3080
Regulatory Contact:	Rich Jansen, Pharm. D. Silver Pine Consulting, LLC richj@s-pineconsulting.com
Trade Names:	Canaveral Pedicle Screw System
Product Class:	Class III
Classification:	21 CFR §888.3070 Pedicle Screw Spinal System, and 888.3050 Spinal Interlaminal Fixation Orthosis
Common Name:	Pedicle Screw System
Product Codes:	NKB, OSH, MNI, MNH, KWP
Panel Code:	87

Indications for Use:
The FloSpine Canaveral Pedicle System is intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.
When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Canaveral Pedicle Screw System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Canaveral Pedicle Screw System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to the posterior approach.
The Canaveral Pedicle Screw System is indicated to provide the surgeon with a minimally invasive approach for posterior spine surgery.

Device Description:
The FloSpine Canaveral Pedicle Screw System comprises non-sterile, single use, titanium alloy components for creating a posterior spinal implant construct. The system attaches to the spine through a component system comprising of pedicle screw assemblies for open and minimally invasive procedures, rods, hooks and set screws. The system is designed to stabilize the spine during the fusion process. The screws are available as monoaxial, uniplanar and polyaxial screws in both cannulated and non-cannulated forms. The rods are available as straight and pre-curved rods and are available in 2 diameters and multiple lengths. Components are made of

Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136. Some rods are made from cobalt chrome which complies with ASTM F1537.

Predicate Device(s):
The FloSpine Pedicle Screw is substantially equivalent to the Synthes Matrix Pedicle Screw System (K120838)*, The Orthofix Matrix Spinal System (K120838) and the U&I Optimal System (K031585).

Performance Standards:
The pre-clinical testing performed includes static and dynamic compression bending, and static torsion per ASTM F1717-10.

Conclusion:
FloSpine concludes that the FloSpine Canaveral Pedicle Screw System is substantially equivalent to the predicate pedicle screw system in regards to indications for use, materials, function, sizes and mechanical test results and raises no new questions of safety or effectiveness.